

AMENDED IN SENATE SEPTEMBER 1, 2015

AMENDED IN SENATE JULY 16, 2015

AMENDED IN SENATE JUNE 19, 2015

AMENDED IN ASSEMBLY APRIL 30, 2015

AMENDED IN ASSEMBLY MARCH 2, 2015

CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL

No. 374

Introduced by Assembly Member Nazarian

February 17, 2015

An act to add Section 1367.244 to the Health and Safety Code, and to add Section 10123.197 to the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

AB 374, as amended, Nazarian. Health care coverage: prescription drugs.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care and makes a willful violation of that act a crime. Existing law also provides for the regulation of health insurers by the Department of Insurance. Existing law imposes various requirements and restrictions on health care service plans and health insurers, including, among other things, requiring a health care service plan *or health insurer* that provides prescription drug benefits ~~to maintain an expeditious process by which prescribing providers, as described, may obtain authorization for a medically necessary~~

~~nonformulary prescription drug, according to certain procedures to utilize a specified uniform prior authorization form or electronic authorization process when requiring prior authorization for prescription drug benefits.~~

~~This bill would require the Department of Managed Health Care and the Department of Insurance to develop a step therapy override determination request form by July, 2016, and would require a prescribing provider to use the form to make a step therapy override determination request. The bill would require a health care service plan or health insurer to respond to a step therapy override determination request within 72 hours for nonurgent requests, or within 24 hours if exigent circumstances exist, as specified. The bill would allow a determination by a health care service plan or health insurer denying a request to be appealed through an independent medical review process, as specified.~~

~~This bill would authorize a request for an exception to a health care service plan's or health insurer's step therapy process for prescription drugs to be submitted in the same manner as a request for prior authorization for prescription drugs, and would require the plan or insurer to treat, and respond to, the request in the same manner as a request for prior authorization for prescription drugs.~~

~~The bill would require the Department of Managed Health Care and the Department of Insurance to include a provision for step therapy exception requests in the uniform prior authorization form specified above.~~

Because a willful violation of these requirements with respect to health care service plans would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: yes.

The people of the State of California do enact as follows:

- 1 *SECTION 1. Section 1367.244 is added to the Health and*
- 2 *Safety Code, to read:*

1 1367.244. (a) A request for an exception to a health care
2 service plan's step therapy process for prescription drugs may be
3 submitted in the same manner as a request for prior authorization
4 for prescription drugs pursuant to Section 1367.241, and shall be
5 treated in the same manner, and shall be responded to by the health
6 care service plan in the same manner, as a request for prior
7 authorization for prescription drugs, including utilization of the
8 grievance process applicable to the denial of a request for prior
9 authorization for prescription drugs specified in Section 1368.

10 (b) The department and the Department of Insurance shall
11 include a provision for step therapy exception requests in the
12 uniform prior authorization form developed pursuant to subdivision
13 (c) of Section 1367.241.

14 SEC. 2. Section 10123.197 is added to the Insurance Code, to
15 read:

16 10123.197. (a) A request for an exception to a health insurer's
17 step therapy process for prescription drugs may be submitted in
18 the same manner as a request for prior authorization for
19 prescription drugs pursuant to Section 10123.191, and shall be
20 treated in the same manner, and shall be responded to by the health
21 insurer in the same manner, as a request for prior authorization
22 for prescription drugs, including utilization of any grievance
23 process applicable to the denial of a request for prior authorization
24 for prescription drugs.

25 (b) The department and the Department of Managed Health
26 Care shall include a provision for step therapy exception requests
27 in the uniform prior authorization form developed pursuant to
28 subdivision (c) of Section 10123.191.

29 SEC. 3. No reimbursement is required by this act pursuant to
30 Section 6 of Article XIII B of the California Constitution because
31 the only costs that may be incurred by a local agency or school
32 district will be incurred because this act creates a new crime or
33 infraction, eliminates a crime or infraction, or changes the penalty
34 for a crime or infraction, within the meaning of Section 17556 of
35 the Government Code, or changes the definition of a crime within
36 the meaning of Section 6 of Article XIII B of the California
37 Constitution.

38 ~~SECTION 1. The Legislature finds and declares all of the~~
39 ~~following:~~

1 ~~(a) Health care service plans and health insurers are increasingly~~
2 ~~making use of step therapy or fail-first protocols, hereafter referred~~
3 ~~to as a step therapy protocol, under which patients are required to~~
4 ~~try one or more prescription drugs before coverage is provided for~~
5 ~~a drug selected by the patient's health care provider.~~

6 ~~(b) Step therapy protocols, when they are based on~~
7 ~~well-developed scientific standards and administered in a flexible~~
8 ~~manner that takes into account the individual needs of patients,~~
9 ~~can play an important role in controlling health care costs.~~

10 ~~(c) In some cases, requiring a patient to follow a step therapy~~
11 ~~protocol may have adverse and even dangerous consequences for~~
12 ~~the patient who may either not realize a benefit from taking a~~
13 ~~prescription drug or may suffer harm from taking an inappropriate~~
14 ~~drug.~~

15 ~~(d) It is imperative that step therapy protocols preserve the health~~
16 ~~care provider's right to make treatment decisions in the best interest~~
17 ~~of the patient.~~

18 ~~(e) Therefore, the Legislature declares it a matter of public~~
19 ~~interest that it require health care service plans and health insurers~~
20 ~~to base step therapy protocols on appropriate clinical practice~~
21 ~~guidelines developed by professional medical societies with~~
22 ~~expertise in the condition or conditions under consideration, that~~
23 ~~patients be exempt from step therapy protocols when inappropriate~~
24 ~~or otherwise not in the best interest of the patients, and that patients~~
25 ~~have access to a fair, transparent, and independent process for~~
26 ~~requesting an exception to a step therapy protocol when~~
27 ~~appropriate.~~

28 ~~SEC. 2. Section 1367.244 is added to the Health and Safety~~
29 ~~Code, to read:~~

30 ~~1367.244. (a) On or before July 1, 2016, the Department of~~
31 ~~Managed Health Care and the Department of Insurance shall jointly~~
32 ~~develop a step therapy override determination request form. On~~
33 ~~and after January 1, 2017, or six months after the form is~~
34 ~~developed, whichever is later, every prescribing provider shall use~~
35 ~~the step therapy override determination request form to request a~~
36 ~~step therapy override determination, and every health care service~~
37 ~~plan shall accept that form as sufficient to request a step therapy~~
38 ~~override determination. The Department of Managed Health Care~~
39 ~~and the Department of Insurance shall develop the step therapy~~
40 ~~override determination request form in a manner that allows it to~~

1 be submitted by a prescribing provider to a health care service plan
2 by an electronic method.

3 (b) A prescribing provider may request a step therapy override
4 determination if he or she determines that a prescription drug that
5 is subject to a step therapy or fail-first protocol by the health care
6 service plan is in the best interest of a patient, based on medical
7 appropriateness.

8 (c) If a health care service plan fails to utilize or accept the
9 override request form, or fails to respond within 72 hours for
10 nonurgent requests, or within 24 hours if exigent circumstances
11 exist, upon receipt of a completed override request from a
12 prescribing provider, pursuant to the submission of the override
13 request form developed pursuant to subdivision (a), the override
14 request shall be deemed to have been granted.

15 (d) A determination by a health care service plan to deny a step
16 therapy override request may be appealed through the independent
17 medical review process established pursuant to Article 5.55
18 (commencing with Section 1374.30), except that the decision of
19 the reviewers shall be rendered within three days of the receipt of
20 the information, as required for an expedited review as specified
21 in subdivision (c) of Section 1374.33.

22 SEC. 3. Section 10123.197 is added to the Insurance Code, to
23 read:

24 10123.197. (a) On or before July 1, 2016, the Department of
25 Insurance and the Department of Managed Health Care shall jointly
26 develop a step therapy override determination request form. On
27 and after January 1, 2017, or six months after the form is
28 developed, whichever is later, every prescribing provider shall use
29 the step therapy override determination request form to request a
30 step therapy override determination, and every health insurer shall
31 accept that form as sufficient to request a step therapy override
32 determination. The Department of Insurance and the Department
33 of Managed Health Care shall develop the step therapy override
34 determination request form in a manner that allows it to be
35 submitted by a prescribing provider to a health insurer by an
36 electronic method.

37 (b) A prescribing provider may request a step therapy override
38 determination if he or she determines that a prescription drug that
39 is subject to a step therapy or fail-first protocol by the health insurer
40 is in the best interest of a patient, based on medical appropriateness.

1 ~~(e) If a health insurer fails to utilize or accept the override~~
2 ~~request form, or fails to respond within 72 hours for nonurgent~~
3 ~~requests, or within 24 hours if exigent circumstances exist, upon~~
4 ~~receipt of a completed override request from a prescribing provider,~~
5 ~~pursuant to the submission of the override request form developed~~
6 ~~pursuant to subdivision (a), the override request shall be deemed~~
7 ~~to have been granted.~~

8 ~~(d) A determination by a health insurer to deny a step therapy~~
9 ~~override request may be appealed through the independent medical~~
10 ~~review process established pursuant to Article 3.5 (commencing~~
11 ~~with Section 10169), except that the decision of the reviewers shall~~
12 ~~be rendered within three days of the receipt of the information, as~~
13 ~~required for an expedited review as specified in subdivision (c) of~~
14 ~~Section 10169.3.~~

15 ~~SEC. 4. No reimbursement is required by this act pursuant to~~
16 ~~Section 6 of Article XIII B of the California Constitution because~~
17 ~~the only costs that may be incurred by a local agency or school~~
18 ~~district will be incurred because this act creates a new crime or~~
19 ~~infraction, eliminates a crime or infraction, or changes the penalty~~
20 ~~for a crime or infraction, within the meaning of Section 17556 of~~
21 ~~the Government Code, or changes the definition of a crime within~~
22 ~~the meaning of Section 6 of Article XIII B of the California~~
23 ~~Constitution.~~